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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,449	06/30/2003	Shiqin Xiong	NTD-2	7138

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,449	XIONG ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Election/Restrictions:

1. Applicants' election with traverse of the invention of Group I (claims 1-9) filed on 13 April 2005 is acknowledged.

The traversal is on the grounds that all the claims in the application involve related subject matter, e.g, human interleukin 17 receptor-like molecules. Thus, Applicant contends that a single search would comprise overlapping subject matter, and would not be undue.

This traversal is considered, but is not found persuasive. As was set forth in the restriction requirement mailed on 13 March 2005, the inventions of Groups I-VI have acquired separate status in the art as shown by their different classifications. Therefore, searching the inventions of all of the Groups together would impose a serious search burden. Searches of the polypeptides and the polynucleotides are not coextensive, because they require entirely different searches of different databases. Thus, since the searches are different, and the inventions have a different status in the art, as evidenced by their different classification, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 are under consideration.

Claims 10-16 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification:

2. The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed.

Claim Rejections Under 35 U.S.C. § 101:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 recites " a host cell comprising...", which encompasses the host cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claim to show the hand of man would obviate this rejection. It is suggested that claim 8 to recite "an isolated host cell". Appropriate correction is require.

Claim Rejections Under 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 1-4, 7-9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1 or 3, said nucleic acid encoding the polypeptide of SEQ ID NO:2 or SEQ ID NO:4, respectively, a vector comprising said nucleic acid, an isolated host cell comprising said vector and a process of producing the encoded polypeptide, does not reasonably provide enablement for "all possible" polynucleotides encoding the polypeptide of SEQ ID NO:2 or 4, or fragments of said

nucleic acids or an isolated polynucleotide capable of hybridizing to and which is at least identical to the nucleic which encodes the polypeptide of SEQ ID NO:2 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 2 and 3 encompass "all possible" nucleic acids which encode the polypeptide of SEQ ID NO:2 or 4, an isolated nucleic acid which is capable of hybridizing to a nucleic acid that encodes the polypeptide of SEQ ID NO:2 or 4, or a fragment of the polynucleotide that encodes the polypeptide of SEQ ID NO:2 or 4. However, the instant specification discloses an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, which encodes the polypeptide of SEQ ID NO:2 and an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:3, which encodes the polypeptide of SEQ ID NO:4. The specification identifies the polypeptides of the instant inventions as being IL-17 receptor like and designates the polypeptide of SEQ ID NO:2 as IL-17RLM-L. The instant specification identifies the polypeptide of SEQ ID NO:4 as being a splice variant and designates it as IL-17RLM-s, (see page 6). The instant specification discloses that the polypeptide of SEQ ID NO:2 (IL-17RLM-L), significantly inhibits the FGF2 or NGF-induced rat pheochromocytocoma PC12 cell differentiation. The specification fails to demonstrate that the polypeptide of SEQ ID NO:4 also inhibits the FGF2 or NGF induced PC12 differentiation. Furthermore, the speciation fails to disclose "all possible" polynucleotides encoding the polypeptide of SEQ ID NO:2 or 4 or a fragment of an

isolated polynucleotide that encodes the polypeptide of SEQ ID NO:2 or 4, or an isolated polynucleotide which hybridizes to and which is at least identical to the polynucleotide which encodes the polypeptide of SEQ ID NO:2 or 4. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. Ex Parte Forman, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). In the instant case, Applicant only disclsoes the polynucleotides of SEQ ID Nos: 1 and 3, encoding the polypeptide of SEQ ID NO:2 or 4, respectively. However, Applicant has not described the characteristics of all the nucleic acids so that one of skill in the art could predictably identify other sequences encoding the polypeptide of SEQ ID NO:2, or 4. Applicant has not described the properties or characteristics of the sequences that are required to encode a functional protein or any other essential characteristics of nucleic acids encoding said polypeptides. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in a nucleic acids encoding a polypeptides which retain the desired activity. Moreover, the instant specification does not disclose a fragment of nucleic acid which encodes the polypeptide of SEQ ID NO:2 or 4. With respect to claim 1 which recites

".....a polynucleotide capable of hybridizing to ..... ", the specification is non-enabling for a polynucleotide which does not hybridize to the desired polynucleotide and only hybridizes after further modification, because Applicant has not taught how to further modify the polynucleotide so that it hybridizes. It has been held that an element is "capable of" performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Therefore, to practice the invention commensurate with the scope of the claims would result in undue experimentation. Moreover, while the skilled artisan would be able to use the polypeptide of SEQ ID NO:2, because it is inhibits FGF2 or NGF induced processes, he or she would not be able to use the polypeptide of SEQ ID NO:4, since its activity is not disclosed.

4b. Claims 1-4, 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

Claims 1-4 and 7-9 are rejected as containing subject matter not described in the specification because they encompass sequences comprising fragments, but require no function or other identifying characteristics. These claims are thus drawn to a genus of polynucleotides that includes sequences of any length, comprising any fragments, and means of expressing them. Applicant has described the polynucleotide sequences of SEQ ID Nos 1, 3. However, the claims encompass polynucleotides that vary

substantially in length and also in composition, with no requirement for any particular structural feature or function. The disclosure of the nucleic acid of SEQ ID NO:1 and 3, does not adequately describe the scope of the claimed genus. A description of a genus of cDNAS may be achieved by means of a recitation of a representative number of cDNAS, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli L illy & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification discloses two isolated cDNA sequences and the translated amino acid sequences. There is no description of the required structural and functional features of all the nucleic acids which encode the polypeptide of SEQ ID NO:2 or 4, or of the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what variations could be tolerated without altering them. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed.

Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus of sequences comprising fragments of the disclosed sequences.

Claim Rejections Under § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 1 is also indefinite in the recitation of "hybridizing", because there is no definition of what are the specific hybridization conditions in the specification. The specification states that the term 'stringent conditions" means hybridization occurs only if there is at least 95% and preferably at least 97% identity between the sequences, (page 6). However, there is no disclosure of said conditions in the specification. Reciting the specific hybridization conditions, which are supported by the specification in the claim would obviate this rejection.

5b. Claim 1 is also indefinite, because sub-part [c] is unclear. It appears that the polynucleotide recited in sub-part [c] hybridizes to the full length of the polynucleotide recited in subpart [a] and [b], and would also be expected to encode to the recited polypeptides. It is not clear how a nucleic acid that hybridizes to a specific nucleic acid that encodes a polypeptide would also encode the same polypeptide. Furthermore, the recitation of "at least" renders the claim unclear. Does this mean that the polynucleotide of sub-part [c] is longer than the polynucleotide that it hybridizes to? The metes and bounds of this claim cannot be ascertained.

5c. Claim 2 recites "...wherein the polynucleotide is DNA, or genomic DNA", however, the distinction between these two forms of DNA is not clear. Appropriate correction is required.

Claims 3-9 are rejected under 35 U.S.C. § 112, second paragraph so far as they depend on claim 1 for the limitations set forth directly above.

Claim Rejections Under 35 U.S.C. § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 1, 2, 4 and 7-9 are rejected under 35 U.S.C §1O2(b) as being anticipated by Wiemann et al, database GenEmbl. Accession Number: AX086664, 09 March 2001; WO0112659). Wiemann et al disclose an isolated nucleic acid that encodes a polypeptide that shares 100% amino acid sequence identity to the polypeptide of SEQ ID NO:4 of the instant invention, a vector comprising said nucleic acid, an isolated host cell comprising said vector, (see copies of the comparison of SEQ ID NO:4, claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A'). Also see pages 101-103 of WO0112659.

Instant claims 1, 2, 4 and 7-9 are drawn to an isolated polynucleotide encoding the polypeptide of SEQ ID NO:4, a vector comprising said nucleic acid, a host comprising said vector and a process of producing the encoded polypeptide.

Therefore, since the Wiemann et al reference meets all these limitations, it anticipates the instant claims 1, 2, 4, 7-9 in the absence of any evidence to the contrary.

Conclusion:

6. No claims are allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is 571-272-0884. The examiner can normally be reached on Monday, Thursday, Friday, 6:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
01 July 2005

JOSEPH MURPHY
PATENT EXAMINER